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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/484,704	01/18/2000	Kelly J. Henrickson	650053.91126	1001

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EXAMINER
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SIEW, JEFFREY

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 05/15/2002

14

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/484,704

Applicant(s)

HENRICKSON ET AL.

Examiner

Jeffrey Siew

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 26 February 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) <sup>6/12, 20, 23</sup> 34-36 is/are pending in the application.
- 4a) Of the above claim(s) <sup>6/12, 20, 23</sup> 34-36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 34-36 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

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1. This application contains claims 6,12,20, & 23 drawn to an invention nonelected with traverse in Paper No. 6. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

### ***Specification***

2. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The limitation of “unequal primer concentration” needs to be inserted.

### ***Terminal Disclaimer***

3. The terminal disclaimer filed on 12/26/02 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US5,744,299 has been reviewed and is accepted. The terminal disclaimer has been recorded.

### ***Double Patenting***

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4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 34 & 36 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,015,664 in view of Sninsky et al (US5,176,995 Jan. 5, 1993).

Claims 34 & 36 are drawn to detecting visual infection by exposing nucleic acid with 5' and 3' primer at unequal concentrations and amplifying and determining amplification by hybridizing a protein linked probe identical to viral sequence.

Claim 1 U.S. Patent No. 6,015,664 are drawn to exposing cDNA to unequal primer concentration pairs for HPIV1,2,3 RSV A& B and Influenzae A & B.

Claim 1 of US 6,015,664 is not drawn to hybridization with protein linked probe.

Sninsky et al teach detection by hybridizing with a probe that is complementary to conserved nucleic acid sequence to genome of virus (see col. 15 line 40-45) and using biotin labeled probes for detection (see col. 16 line 9).

One of ordinary skill in the art would have been motivated to apply Sninsky et al's teaching of biotin labeled probes to the method claim of US6,015,664 in order to quickly detect

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amplified virus. As biotin label probes allow rapid colorization, it would have been prima facie obvious to apply Sninsky et al's teaching of biotin probes to the detection method claim 1 in order to rapidly detect viral sequences without the use of harmful radioactivity.

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***Claim Rejections - 35 USC § 103***

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. Claims 34-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Karron et al (J. Clinical Micro vol. 32 no. 2 pp. 484-88 1994) in view of Sninsky et al (US5,176,995 Jan. 5, 1993).

Karron teach PCR rapid detection of HPIV-3 of HN gene using RT-PCR (see whole doc. esp. abstract).

Karron do not teach protein linked probe nor unequal primer concentration.

Wu et al teach a method of performing polymerase chain reaction using unequal primer concentration in which primer pairs is at least 2:1 (see abstract). They teach a polymerase reaction in which is denaturation is performed thirty times at 95C.

Sninsky et al teach detection by hybridizing with a probe that is complementary to conserved nucleic acid sequence to genome of virus (see col. 15 line 40-45) and using biotin labeled probes (see col. 16 line 9).

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One of ordinary skill in the art would have been motivated to apply Wu et al's primer ratios to Karron's method in order to successfully amplify the virus nucleic acid. As Wu et al teach that unequal primer ratio of 2:1 would lead to successful amplification, it would have been prima facie obvious to apply Wu et al's ratios to Karron's method in order to maximize the amplification of viral nucleic acid.

Moreover, one of ordinary skill in the art would have been motivated to apply Sninsky et al's teaching of biotin labeled probes to Karron's detection method in order to quickly detect amplified virus. As biotin label probes allow rapid colorization, it would have been prima facie obvious to apply Sninsky et al's teaching of biotin probes to the Karron's detection method in order to rapidly detect viral sequences without the use of harmful radioactivity.

### REBUTTAL

8. The response filed 2/26/02 and affidavit filed 2/26/02 have been fully considered and deemed not persuasive. The response states that in the that the Wu et al do not teach a double stranded product is formed but that asymmetric PCR forms a single stranded product. While the office does not disagree that a single stranded product is formed, double stranded product is also formed during the course of amplification. The excess primer does allow single stranded to be formed but does not mean that **ONLY** single stranded product is formed. Wu et al also states present invention is useful for detection of specific nucleic acid having two complementary strands (see page 4 line 41) and that double stranded product is formed (see (col. 5 line 11-12). Moreover, the breadth of the claims do not recite that only double stranded product is formed but rather a double stranded product is formed which Wu et al do teach. The claims also do not

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explicitly recite a multiplex reaction but rather still may reasonably read on single pair of primers. The rejections are maintained.

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### **SUMMARY**

9. No claims allowed.

### ***Conclusion***

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.


11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Siew whose telephone number is (703) 305-3886 and

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whose e-mail address is Jeffrey.Siew@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route. The examiner is on flex-time schedule and can best be reached on weekdays from 6:30 a.m. to 3 p.m. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703)-308-1119.

Any inquiry of a general nature, matching or filed papers or relating to the status of this application or proceeding should be directed to the Monica Graves for Art Unit 1637 whose telephone number is (703)-306-2938.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Center numbers for Group 1600 are Voice (703) 308-3290 and Before Final FAX (703) 872-9306 or After Final FAX (703) 30872-9307.

  
JEFFREY SIEW  
PRIMARY EXAMINER

May 13, 2002